

CROSS-REFERENCE TO RELATED APPLICATION

This application claims the benefit of U.S. Provisional Patent Application No. 60/141,753 filed June 30, 1999, where this provisional application is incorporated herein by reference in its entirety.

REMARKS

This amendment is filed in response to the Office Action mailed November 2, 2001 (Paper No. 16). Claims 11-16 are currently being considered and the species of SEQ ID NO:4 was elected. The claims have not been amended.

Applicants acknowledge the withdrawal of the rejections as summarized at pages 2 and 3 of the Office Action. Applicants have amended the specification to make reference to provisional application Serial No. 60/141,753.

The Examiner maintained the rejection of claims 11-16 under 35 U.S.C. § 101 because the claimed invention allegedly is not supported by a credible, specific and substantial asserted utility or a well-established utility. Claims 11-16 were also rejected under 35 U.S.C. § 112, first paragraph, as one skilled in the art allegedly would not know how to use the claimed invention in view of the asserted lack of utility. Applicants respectfully traverse this rejection.

In compliance with the Utility Guidelines, the Examiner imposed a rejection under 35 U.S.C. § 101, and the burden shifted to applicants to come forward with evidence that (1) identifies a specific and substantial utility for the claimed invention and (2) shows that this utility was established at the time of filing. Applicants submit that they have met this burden, as evidenced by the arguments and evidence submitted in the response filed on August 14, 2001. These arguments and evidence are incorporated but not reiterated herein.

In reply, the Examiner states that "homology is insufficient unless accompanied by assays of a protein's function." (Paper No. 16, page 4, lines 18-19.) Although the Examiner has cited a few examples of proteins with high homology yet disparate function, one of ordinary skill in the art will nevertheless proceed on the premise that high homology is predictive of a protein's structure and function. To support applicants' position, applicants submit herewith a Declaration under 37 C.F.R. § 1.132 by David Duhl in which Dr. Duhl declares that, based on the

homology results, one of skill in the art would believe that applicants' SEQ ID NO:4 represents a human plasmolipin protein.

Having identified a novel human plasmolipin molecule, applicants need not disclose, for example, "knock-in" or knock-out" phenotypes, binding assays, or diseases related to the disclosed protein, as suggested at pages 5-6 of the Office Action. Instead, the plasmolipin protein is used generally as is known in the art for known plasmolipin proteins, as discussed at, for example, page 5, lines 9-25 of the specification.

For the foregoing reasons, reconsideration and withdrawal of the rejection under 35 U.S.C. § 101 are respectfully requested.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "**Version With Markings to Show Changes Made.**"

All of the claims remaining in the application are now clearly allowable. Favorable consideration and a Notice of Allowance are earnestly solicited.



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PATENT TRADEMARK OFFICE

Respectfully submitted,

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Enclosure:

Declaration Under 37 C.F.R. § 1.132 (David Duhl)

VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Specification:

The following paragraph was added before the paragraph entitled "Technical Field" at page 1, line 3:

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